

REMARKS

The Examiner has rejected claims 1-3, 5-6, 8-11, and 13-15 under 35 USC 103(a) as being unpatentable over U.S. 4,958,736 to Urheim in view of U.S. 3,568,828 to Lerner. In this rejection, the Examiner has stated that Urheim discloses a package for enabling compliance with a regimen of dosage of medication over a period of time, with the package comprising a backing (16) having an array of receivers (12) including columns and rows along with a plurality of tablets (21 or 22) and indicia (18, 20) disposed adjacent the columns and rows for displaying common days and successive weeks.

Urheim does not provide for a plurality of sets of tablets with each tablet in a set having a common dose of medication and a different dose than a tablet of a different set.

In view of this lack of teaching, the Examiner reaches to Lerner for a disclosure of providing tablets of different dosages at different times in the course of a regimen. The Examiner then concludes that to modify the package of Urheim employing tablets of different dosages would have been obvious in view of Lerner.

Accordingly, the Examiner has utilized hindsight to reconstruct the invention. It is well known that patentability of an invention is not viewed with hindsight; whether individual elements of a combination are old begs a question; thus, where the invention sought to be patented resides in a combination of old elements, inquiry is whether bringing them together was obvious, not whether one of ordinary skill, having the invention before him would find it

obvious through hindsight to construct the invention from the elements of the prior art. *In re Warner and Warner*, 154 USPQ 173 (CCPA 1967).

Every invention is obvious after it has been made, and to no one more so than an expert in the field. It is so easy, once the teaching of a patent is known, to say, "I could have done that". However, before the assertion can be given any weight, one must have a satisfactory answer to the question, "Why didn't you?".

That is, a requirement prevents the use of an inventor's disclosure as a blueprint for piecing together prior art to defeat patentability. Ecolochem, Inc. v. Southern California Edison, 56 USPQ 2d 1050 (Fed. Cir. 2000); Iron Grip Barbell Co. v. USA Sports, Inc., 73 USPQ 2d 1225 (CAFC 2004); Syntax (USA) LLC v. Apotex, Inc., 74 USPQ 2d 1823 (CAFC 2005).

Where an invention is contended to be obvious based upon the combination of elements across different references, cases require that there be a suggestion, motivation, or teaching to those skilled in the art for such combination. *In re Fine*, 5 USPQ 2d 1596 (Fed. Cir. 1988).

Lerner at column 2, beginning at line 43, states that dosage units are preferably packaged in a dispensing device, e.g., a folder or sequential plastic dispenser, and arranged in a manner which facilitates the orderly daily administration and sequence.

However, there is no suggestion of providing sets of tablets with each tablet in a set having a common dose of medication and a different dose than a tablet of a different

set which each of the sets being disposed in receivers of one of an adjacent roll and adjacent column such as presently claimed. The claim structure and disclosure of the present application must be used as a blueprint for piecing together the prior art as suggested by the Examiner.

Certainly, the teaching of Lerner with regard to a titration package are so broad as to be not enabling.

It has been stated that even if the claimed invention is disclosed in a printed publication, that disclosure will not suffice as prior art if it were not enabling. *In re Donohue*, 226 USPQ 619 (CAFC 1985); *In re Borst*, 145 USPQ 554 (CCPA 1965).

It is well settled that prior art must be sufficiently described in claimed invention to have placed the public in possession of it. *In re Sasse*, 207 USPQ 107 (CCPA 1980); *In re Samour*, 197 USPQ 4 (CCPA 1978); Redding and Bates Construction Co. v. Baker Energy Resources, 223 USPQ 1168 (Fed. Cir. 1984).

Such possession is effected if one of ordinary skill in the art would have combined the reference description of the invention with his own knowledge to make the claimed invention. *In re LeGrice*, 133 USPQ 365 (CCPA 1962).

The Applicants submit that for prior art to be pertinent it must be enabling - it must place the public in possession of the invention. Items which do not sufficiently teach, how to make, use and practice the invention are not prior art to the invention. Akzo N.V. v. U.S. Int'l Trade Commission, 1 USPQ 1241 (Fed. Cir. 1986); *In re Hall*, 228 USPQ 453 (Fed.

Cir. 1986) further stating that in order to be prior the prior art reference must teach the claimed invention without further research or experimentation. See also *In re Pyne*, 203 USPQ 245 (CCPA 1979) and Fizer, Inc. v. International Rectifier Corp., 207 USPQ 397 (Dist. Ct. C.D. California 1980).

The Applicants submit that the Lerner reference, while teaching the advantages of utilizing various doses, provides no enabling teaching as to the structure presently claimed. Accordingly, the Applicants submit that the structure of the present invention which includes the combination of tablets of various doses is not obvious in view of the references cited and certainly improperly combined due to hindsight considerations hereinabove set forth.

Claims 1-3, 5-6, 8-11, and 13-17 have been finally rejected by the Examiner under 35 USC 103(a) as being unpatentable over EP 0852208 in view of one of Urheim and CA 2,218,470. In this rejection, the Examiner has stated that the EP reference discloses it was known to provide tablets of different dosage at different times in the course of a regime and that Urheim and the Canadian patent each disclose a package for enabling compliance with a regime of dosage and medication over a period of time.

The Applicants reiterate the hereinabove set forth arguments for traversing the rejection of the claims on the basis of Urheim and Lerner. That is, hindsight is a primary motive for the combination and further the combination does not teach or suggest the specific plurality of sets of tablets in accordance with the present invention with each set having a common dose of medication and a different dose than a tablet

of a different set. Accordingly, the Examiner has not made a prima facie case of obviousness.

Claims 4, 7, 12, and 16 have been finally rejected by the Examiner under 35 USC 103(a) as being unpatentable over the art as applied to claims 3, 16, 11, 15, and 18 and further in view of U.S. 5,747,545 to Lipton. The Examiner relies on Lipton for a teaching of the use of memantine in a gradually increasing dosage to teach glaucoma. However, the Lipton, et al. reference is silent with regard to any of the structure set forth in the independent claims from which claims 4, 7, 12, and 16 depend. Accordingly, a prima facie case of obviousness has not been made.

Claim 17 has been rejected by the Examiner under 35 USC 103(a) as being unpatentable over Urheim in view of Lerner. The Examiner has stated that to merely provide the package of the previously described combination would have been obvious. Accordingly, it is not obvious if the package is otherwise patentable as hereinabove argued.

Claim 17 has been further finally rejected under 35 USC 103(a) as being unpatentable over WO 97/03896 in view of one of Urheim and CA 2,218,470. Again, the Examiner has stated that to merely provide the package of the previously described combination would have been obvious. The Applicants resubmit the arguments hereinabove set forth for traversing this rejection.

Claims 18-25 has been finally rejected by the Examiner under 35 USC 103(a) as being unpatentable over EP 0852208 in view of one of either Urheim or CA 2,218,470, and Lipton. In

traverse of this rejection, the Applicants resubmit hereinabove set forth arguments.

In view of the arguments hereinabove set forth, it is submitted that each of the claims now in the application define patentable subject matter not anticipated by the art of record and not obvious to one skilled in this field who is aware of the references of record. Reconsideration and allowance are respectfully requested.

Respectfully submitted,



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